

#### **ATTORNEY DOCKET No.: 2003946-0110 (ANDI/US)**

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Boivin et al.

Examiner:

NYA.

Serial No:

10/507,067

Group Art Unit:

NYA

Filing Date: Corresp. to:

September 8, 2004 PCT/US03/07377

Int. Filing Date: March 7, 2003 Earliest Priority: March 8, 2002

Title:

MACROCYCLIC COMPOUNDS USEFUL AS PHARMACEUTICALS

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

Certificate of Mailing

I certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA

22313-1450

November  $\mathcal{E}$ , 2004 Date

Kathy Hart Gagnon

1

Typed or Printed Name of person signing certificate

TRANSMITTAL LETTER

In regard to the above-referenced patent application, enclosed please find the following:

- 1. Statement Filed Pursuant To The Duty Of Disclosure Under 37 CFR §§1.56, 1.97 and 1.98 (6 pp.);
- 2. Form PTO-1449 (2 pgs.);
- 3. Cited Art (21 References); and
- 4. Return-Receipt Postcard.

Please charge any additional fees associated with this filing, or apply any credits, to our Deposit Account No. 03-1721.

Respectfully

Date: November \( \frac{\gamma}{\quad} \), 2004

Nadège M. Lagneau, Ph.D.

Reg. No. 51,908

PATENT GROUP

CHOATE, HALL & STEWART

53 State Street

**Exchange Place** 

Boston, MA 02109

Telephone: (617) 248-5000 Facsimile: (617) 248-4000

U.S.S.N. 10/507,067 3763122 1.DOC

Page 1 of 1

Attorney Docket No.: 2003946-0110

Client Reference: ANDI/US



# DT02 Rec'd PCT/PTO

: 0 NOV 2004

ATTORNEY DOCKET No.: 2003946-0110 (ANDI/US)

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Boivin et al.

Examiner:

NYA.

Serial No:

10/507,067

Group Art Unit:

NYA

Filing Date:

September 8, 2004

Corresp. to:

PCT/US03/07377 Int. Filing Date: March 7, 2003

Earliest Priority: March 8, 2002

Title:

Sir:

MACROCYCLIC COMPOUNDS USEFUL AS PHARMACEUTICALS

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Certificate of Mailing

I certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA

22313-1450

November 5. 2004

Date

Kathy Hart Gagnon

Typed or Printed Name of person signing certificate

STATEMENT FILED PURSUANT **DUTY OF DISCLOSURE UNDER 37 CFR 88** 

7 AND 1.98 جر

Pursuant to the duty of disclosure under 37 CFR §§ 1.50

consideration of this Information Disclosure Statement.

#### Type of Statement

The present Information Disclosure Statement is:

[X]An original Information Disclosure Statement; &

[] A supplemental Information Disclosure Statement.

U.S.S.N. 10/507,067 3763126 1.DOC

age 1 of 6

Attorney Docket No.: 2003946-0110

Client Reference: ANDI/US

## Compliance with 37 CFR § 1.97

The present Information Disclosure Statement is being filed:

[ <b>X</b> ]	Pursuant to 37 CFR § 1.97(b); no fee or certification is required:				
	[X]	Withir	three months of the filing date of a national application other than		
		a conti	nued prosecution application under § 1.53(d);		
	[]	Withir	three months of the date of entry of the national stage as set forth		
		in § 1.	491 in an international application;		
•	[]	Before	e the mailing of a first Office action on the merits; or		
	[]	Before	the mailing of a first Office action after the filing of a request for		
		contin	ued examination under § 1.114.		
[]	Pursuant to 37 CFR § 1.97(c) after the dates listed above but before the n				
date of any of a final action under § 1.113, a notice of allowance under					
	an action that otherwise closes prosecution in the application; Applicant hereby				
	either:				
	[]	Certifi	es that either:		
		[]	Each item of information contained in the information disclosure		
			statement was first cited in any communication from a foreign		
			patent office in a counterpart foreign application not more than		
			three months prior to the filing of the information disclosure		
			statement; or		

Attorney Docket No.: 2003946-0110 Client Reference: ANDI/US

		[]	That no item of information contained in the information	
			disclosure statement was cited in a communication from a foreign	
			patent office in a counterpart foreign application, and, to the	
			knowledge of the person signing the certification after making	
			reasonable inquiry, no item of information contained in the	
			information disclosure statement was known to any individual	
			designated in § 1.56(c) more than three months prior to the filing of	
			the information disclosure statement; or	
	[]	Includ	es herewith the fee set forth in § 1.17(p).	
]	Pursuant to 37 CFR § 1.97(d), after the mailing date of any of a final action un			
	§ 1.11	3, a noti	ice of allowance under § 1.311, or an action that otherwise closes	
	prosecution in the application; Applicant hereby both:			
	[]	Certifi	es that either:	
		[]	Each item of information contained in the information disclosure	
			statement was first cited in any communication from a foreign	
			patent office in a counterpart foreign application not more than	
			three months prior to the filing of the information disclosure	
			statement; or	
		[]	That no item of information contained in the information	
			disclosure statement was cited in a communication from a foreign	
			patent office in a counterpart foreign application, and, to the	
			knowledge of the person signing the certification after making	

Attorney Docket No.: 2003946-0110 Client Reference: ANDI/US

reasonable inquiry, no item of information contained in the

information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement; and

[] Includes herewith the fee set forth in § 1.17(p).

#### Content of the Information Disclosure Statement

Applicant hereby makes of record in the above-identified application the reference(s) listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicant includes copies of references as indicated below:

- [X] A copy of each cited reference not indicated with a † is included;
- Copies of references indicated with a † on the attached form PTO-1449 [X] are not included because the requirement to provide copies was waived pursuant to USPTO OG Notice of 8/5/03.
- [ ] Copies of English translations of one or more non-English references are included.

Page 4 of 6

Attorney Docket No.: 2003946-0110

Client Reference: ANDI/US

Applicant hereby makes the following additional information of record in the aboveidentified application:

Applicant certifies that the Information Disclosure Statement either:

- Does not contain non-English language citations;
- [ ] Includes one or more translations of a non-English citation; or
- [X] Does contain non-English language citations, of which the following is a concise explanation:

#### Abstracts in English are provided.

#### Remarks

The submission of this Information Disclosure Statement should not be construed as a representation that a search has been made.

The submission of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b).

The submission of this Information Disclosure Statement shall not be construed as a representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 USC § 102.

It is respectfully requested that:

- 1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
- 2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited patent(s) and publication(s) has (have) been fully considered by the Patent and Trademark Office during the examination of this application; and

Attorney Docket No.: 2003946-0110

Client Reference: ANDI/US

3. The citations for the patent(s) and publication(s) be printed on any patent which issues from this application.

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited reference(s).

Respectfully submitted,

CHOATE, HALD& STEWART

Nadège M. Lagneau, Ph.D.

Reg. No.: 51,908

PATENT GROUP CHOATE, HALL & STEWART Exchange Place 53 State Street Boston, Massachusetts 02109

Tel: (617) 248-5000 Fax: (617) 248-4000

Dated: November 2, 2004

Attorney Docket No.: 2003946-0110 Client Reference: ANDI/US

U.S.S.N. 10/507,067 3763126\_1.DOC Page 6 of 6

Form PTO-144 (REV. 8-03)	Patent ar	partment of Commerce and Trademark Office	Attorney Docket In re Application 1 2003946-0110 10/507,067 (ANDI/US)						
NOV 1 0 20C4 &	INFORMATIO		Applicant: Boivin et al						
The second	DISCLOSURE STAT (Use several sheets if n		Filing Date: Group:						
U.S. PATENT	<u> </u>	ecessary)	September 8, 2004 NYA						
	DOCUMENTS	1.							
Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Subclass				
	† 5,674,892	Giese, et al.	October 7, 1997	514	450				
	† 5,727,726	Giese, et al	March 17, 1998	514	449				
	† 5,795,910	Giese, et al.	August 18, 1998	514	450				
	† 6,265,603 B1	Lewis, et al.	July 24, 2001	560	9				
U.S. PATENT	APPLICATIONS								
Examiner's Initials:	Serial Number:	Applicant:	Filing Date:	Group:	Art Unit:				
	†10/657,910	Chiba, et al.	September 9, 2003		1614				
FOREIGN PA	TENT DOCUMENTS								
Examiner's Initials	Document No.	Country	International Publication Date	Translation					
				Yes	No				
· · · · · · · · · · · · · · · · · · ·	EP 0 606 044 A1	EP	November 29, 1993						
	GB 2 323 845 A	UK	October 7, 1998						
	JP 8- 40893	JP	February 13, 1996		X				
	WO 96/13259	PCT	May 9, 1996						
	WO 00/38674	PCT	July 6, 2000						
· · ·	WO 00/39314	PCT	July 6, 2000						
	WO 01/36003 A2	PCT	May 25, 2001						
	WO 02/48136 A1	PCT	June 20, 2002		X				
OTHER DOC			<u> </u>						
Examiner's Initials	Citation (Including Author, Title, Date, Pertinent Pages, Etc.)								
	Copy of International Search Report for PCT/US03/07377.								
	Agatsuma, et al., "Revised Structure and Stereochemistry of Hypothemycin", Chem. Pharm. Bull.; 41(2): 373-375 1993.								
	Chen, et al., "Activation of p38 MAP kinase and ERK are required for ultraviolet-B induced c-fos gene expression in human keratinocytes", Oncogene, 18: 7649-7476, 1999.								
	Dombrowski, et al., "Production of a Family of Kinase-inhibiting Lactones from Fungal Fermentations", J. Antibiot., 52(12): 1077-1085, 1999.								

Form PTO-144	9 U.S. Department of Commerce	Attor	ney Docket	In re Application No.			
(REV. 8-03)	Patent and Trademark Office	1	46-0110	10/507,067			
	INFORMATION	<u> </u>	DI/US)				
	INFORMATION DISCLOSURE STATEMENT	Applicant: Boivin et al					
	(Use several sheets if necessary)	1	g Date: mber 8, 2004	Group: NYA			
	Ellestad, et al., "New Zearalenone Related Macro						
	Fungus", J. Org. Chem., 43(12):2339-2343, 1978						
	Li, et al., "Rays and arrays: the transcriptional program in the response of human epidermal keratinocytes to UVB illumination", <i>The FASEB Journal</i> , Article 10.1096/fj.01-0172fje, published online September 17, 2001.						
	Kastelic, et al., "Induction of Rapid IL=1β mRNA Degradation in THP-1 Cells Mediated Through the AU-Rich Region in the 3'UTR by a Radicocol Analogue", <i>Cytokine</i> 8(10): 751-761, 1996.						
•	Matsuoka, et al., "Inhibition of HgCl <sub>2</sub> -induced mitogen-activated protein kinase activation by LL-Z1640-2 in CCRF-CEM cells", Eur. J. Pharmacol., 409(2): 155-158, 2000.						
	Rawlins, et al., "Inhibition of endotoxin-induced zeaenol and other fungal resorcylic acid lactones 1999.		-				
•	Tak, et al., "NF-κB-a key role in inflammatory diseases", J. Clin. Investigation, 107(1): 7-11, 2001.						
ú	Takehana, et al., "A radicicol-Related Macrocyclic Nonaketide Compound, Antibiotic LL-Z1640-2, Inhibits the JNK/p38 Pathways in Signal-Specific Manner", <i>Biochem. Biophys. Res. Commun.</i> , <b>257</b> (1): 19-23, 1999.						
	Tatsuta, et al., "The First Total Synthesis of a Macrocyclic Anti-protozoan, LL-Z1640-2", Chem. Lett., Vol. 2, 172-173, 2001.						
	Yamamoto, et al., "Therapeutic potential of inhibition of the NF-κB pathway in the treatment of inflammation and cancer", J. Clin. Investigation, 107(2), 135-142, 2001.						
1							
•							
				<u> </u>			
EXAMINER			DATE CONSIDER	ED			
	nitial if citation considered, whether or not citation						
through citation	if not in conformance and not considered. Include	е сору	of this form with nex	t communication to			

applicant.